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10/584,321	08/02/2007	Alun Pryce James	292709US0PCT	9086
22850 7590 06/12/2009 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER INYARD, APRIL C	
			ART UNIT	PAPER NUMBER
			1794	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/584,321	Applicant(s) JAMES ET AL.	
	Examiner APRIL C. INYARD	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1794

DETAILED ACTION

Priority to provisional application 60552740 filed 03/15/04 and to foreign application EP03258227.2 filed 12/29/2003 is acknowledged.

Claim Objections

1. **Claims 8-9** are objected to because of the following informalities: Applicant recites “used in an amount from... **1** per ton of plant material”, where it appears that Applicant intended for the bolded and underlined **1** to mean liters. In this case, the “**1**” looks like the numeral 1, and it is suggested that for clarity the Applicant amend the claim(s) to reflect the desired volumetric unit as liters (l). Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1, 3-5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by**

Wright et al. (WO 94/06294):

Wright discloses a disinfecting process in which a substrate of chopped lettuce, a harvested plant material, is contacted with an aqueous solution of at least one aliphatic peracid and at least one aliphatic acid and hydrogen peroxide (*Examples 1 and 5; Claims 1 and 5*), where

Art Unit: 1794

the composition of the aqueous solution specifically comprises 1-4% peracetic acid, 2-20% hydrogen peroxide, and 8-47% acetic acid (*Formulations A, B, and C*).

Therefore Wright teaches a process that meets the limitations of **Claims 1, 3-5, and 7**.

4. **Claims 1-6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Doyle et al. (WO 99/44444):**

Regarding **Claim 1**, Doyle teaches a method to reduce the numbers of pathogenic bacteria on the surfaces of fresh fruits and vegetables, especially by inactivating enteric pathogens by washing or soaking such food items in a solution with a pH below 3.5, comprising 1.5% lactic acid, plus 0.1-3% hydrogen peroxide and 0.1% sodium benzoate, where the lactic acid in the solution can be substituted by one or more of acetic, malic, propionic, tartaric, mandelic, and phosphoric acid at similar concentration and pH (*p. 3, lines 9-26; pp. 5-6, lines 23-27 and 1-4*).

Doyle therefore teaches a process for disinfection of a harvested plant material using a liquid composition containing a peroxygen (hydrogen peroxide) and at least one preservative (sodium benzoate), and meets the limitations of **Claim 1**.

Regarding **Claim 2**, Doyle teaches the process of disinfecting harvested fruits and vegetables, where the Examiner takes the position that such commonly harvested fruits and vegetables are known to include several of the plant materials as claimed by Applicant, and deems that Doyle meets the limitations of Applicant's claimed Markush group. The Examiner further takes the position that any treated fruit and vegetable suitable for human consumption is capable of being fed to animals, and therefore meets Applicant's recitation of "animal feed".

Art Unit: 1794

Therefore, the Examiner takes the position that Doyle teaches a process that meets the limitations of Claim 2.

Regarding **Claim 3**, as discussed above, Doyle teaches a process wherein the liquid composition includes hydrogen peroxide and thus meets the instant limitations.

Regarding **Claim 4**, as discussed above, Doyle teaches a process wherein the liquid composition includes an organic acid or salt thereof including sodium benzoate and lactic acid, where other organic acids may be substituted for lactic acid including acetic, malic, propionic, tartaric, mandelic, and phosphoric acid. Thus Doyle meets the limitations of the instant claim.

Regarding **Claims 5 and 10**, Doyle teaches that the pH of the liquid composition is below 3.5, preferably from about 0.5 to about 3.5 (*p. 3, lines 21-22*). Thus, Doyle teaches a pH of the aqueous solution that is encompassed by Applicant's claimed range.

The percentages of each component in the solution are given in (v/v %) by Doyle, whereas the Applicant appears to claim (w/v %). However, Doyle teaches combined use of Applicant's claimed peroxygen and organic acid preservatives in a process to treat harvested plant material, and the pH of Doyle's liquid composition meets Applicant's claimed limitations. Therefore, since the composition taught by Doyle both uses the chemical agents and has a pH as claimed by Applicant, the Examiner takes the position that the chemical agents in the liquid composition taught by Doyle will thus inherently have Applicant's broadly claimed wt%. Applicant bears the responsibility for proving that the reference composition does not possess the characteristics recited in the claims. *See MPEP 2112*.

Art Unit: 1794

Regarding **Claim 6**, as discussed above, Doyle teaches a process that is deemed to meet the limitations of Claim 5, wherein the peroxygen compound is hydrogen peroxide and a preservative is sodium benzoate.

5. Claims 1-3, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Bo et al. (EP 335242):

Regarding **Claim 1**, Bo teaches a process for the preservation of animal feed wherein a liquid mixture of formic acid and hydrogen peroxide is added to fresh, newly harvested fodder (*Abstract; p. 3, lines 27-49; Examples 1 and 2, Claim 6*).

The hydrogen peroxide component of the liquor taught by Bo is considered to correspond to Applicant's liquid composition containing at least one peroxygen compound.

Therefore Bo teaches a process that meets the limitations of the instant claim.

Regarding **Claim 2**, the newly harvested fodder taught by Bo is animal feed that includes grass and direct-cut timothy grass (*Examples 1-2*) and thus meets the limitations of the instant claim.

Regarding **Claim 3**, as discussed above, the peroxygen compound taught by Bo is hydrogen peroxide and thus meets the limitations of the instant claim.

Regarding **Claim 8**, Bo discloses addition of the preservative and peroxygen liquor at a rate of 5 liters per ton of grass (*Example 2*). This ratio is encompassed by Applicant's range of 0.5 to 10 liters per ton of plant material, and thus Bo meets the limitations of the instant claim.

Regarding **Claim 10**, Bo teaches that the process of treating fodder decreases the initial pH of the fresh, newly harvested fodder to 4.5 or less (*p. 6, line 35; Claim 2*), and discloses that

Art Unit: 1794

the pH of the liquors used to treat the fodder ranges from 3.93-4.3. The pH range disclosed by Bo is encompassed by Applicant's claimed range of 1-7, and thus Bo meets the limitations of the instant claim.

6. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Glabau (US Patent No 3,531,294):

Claim 1: Glabau teaches a process wherein a whey, non-fat milk and defatted soy flour mixture is subjected to an oxidation treatment by suspended the mixture in a liquid composition containing calcium peroxide and lactic acid or similar organic acid (*Col 2, lines 1-8; Claims 5-6*).

Claim 2: The Examiner takes the position that as the process for treating the mixture as taught by Glabau is safe for human consumption, that such material is likewise safe and capable of being fed to an animal.

Thus the soy flour disclosed by Glabau is considered to meet Applicant's limitations of "harvested plant material", specifically a plant material that is derived from legumes, and is capable of being animal feed.

Claims 3-4: Glabau discloses combined use of calcium peroxide, a metallic peroxide, and lactic acid or other similar organic acids.

Therefore, Glabau discloses a process that meets the limitations of instant Claims 3-4.

Art Unit: 1794

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doyle as evidenced by Rossmore (Ch. 11.5, p. 320, Handbook of Biocide and Preservative Use, Springer, 1995) OR in view of Wright.**

As discussed above, Doyle teaches a process that meets the limitations of Claim 1.

The Examiner takes the position that Doyle further meets the limitations of Claim 5 because Doyle uses the chemical agents as claimed by Applicant, where the pH of the solution disclosed by Doyle meets Applicant's limitations of Claim 10.

Regarding Claim 7, Doyle does not specifically disclose a mixture of peracetic acid, hydrogen peroxide, and acetic acid; but as discussed above, Doyle does disclose that suitable substitutions for lactic acid include acetic acid.

Art Unit: 1794

As evidenced by Rossmore, one having ordinary skill in the art would readily recognize that an aqueous mixture of acetic acid and hydrogen peroxide will produce peracetic acid, where such equilibrium mixtures of acetic acid, hydrogen peroxide, peracetic acid (4-5% or 15%), and water are commonly known disinfectants commonly used in the food industry (*p. 320*).

Regarding the wt% limitations in Claims 5 and 7, the Examiner points out that as it is known in the art that disinfecting solutions containing 4-5% or 15% peracetic acid, about 85-96% of the remaining solution will be comprised of acetic acid, hydrogen peroxide, and water.

Therefore, the Examiner takes the position that solutions of peracetic acid, hydrogen peroxide, and acetic acid present in the wt% ranges as claimed by the Applicant are known in the art of food grade disinfectants as evidenced by Rossmore.

It would have therefore been obvious at the time the invention was made to one having ordinary skill in the art to modify the liquid composition as disclosed by Doyle to include acetic acid and thus peracetic acid by reaction with hydrogen peroxide, because Doyle clearly teaches that this is a simple substitution of one known organic acid, lactic acid, for another, acetic acid, and that such antimicrobial solutions are oxidizing solutions that rapidly disinfect, where as evidenced by Rossmore, peracetic acid/acetic acid/peroxide disinfecting solutions are well-known in the art as commercially available solutions safe for use in the food industry that typically contain concentrations of each agent in a wt% range that meets the limitations of **Claims 5 and 7**.

Additionally, as discussed above, Wright discloses a process for treating plant material with a biocidal aqueous solution that meets Applicant's claimed compositional ranges, that are suitable for maintaining long term anti-microbial activity in treated materials (*p. 2, lines 17-19*).

Art Unit: 1794

It would have therefore been obvious at the time the invention was made to one having ordinary skill in the art to modify the composition as disclosed by Doyle to use peracetic and acetic acids as the acid preservative component mixed with hydrogen peroxide because this results in a disinfected plant material where such solutions provide anti-microbial activity over an extended period of time and reduce the amount of treatments and thus materials required.

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bo in view of Nakanish (US Patent No. 3,784,699).

As discussed above, Bo teaches a process that meets the limitations of Claims 1 and 8.

Bo teaches that the liquid composition is applied in an amount of 5 liters per ton of plant material.

Bo does not specifically teach that the composition is applied in an amount ranging from 1 to 3 liters per ton of plant material.

However, the Examiner takes the position that the level and completeness of disinfection of the food material will depend both on the type of plant material, and the liquid composition, concentration and the pH of the chemical agents, in the liquid solution, and further, the dilution of the concentrated liquid solution used.

Additionally, in an analogous art of inhibiting microbial growth in foods, Nakanishi discloses addition of benzoic acid and its salts in combination with other disinfectants or preservatives such as sorbic acid, acetic acid and its derivatives, and hydrogen peroxide (*Col. 1, lines 22-26; Col 2, lines 54-71*), and that when an antimicrobial agent is added to foods, including fruits and vegetables (*Col 2, lines 21-41*), it must have low toxicity to humans and/or

Art Unit: 1794

animals and should have no adverse effect upon the flavor of the foods at the levels at which they are employed (*Col 1, lines 60-64*).

It would have therefore been obvious at the time the invention was made it would be obvious to one having ordinary skill in the art to modify the process of Bo by adjusting the amount of the liquid composition used to treat the plant material because addition of such agents to food for human or animal consumption must be in an amount that has no adverse effect upon the flavor of the foods and present little to no toxicity, and thus it would be within the level of ordinary skill to modify such parameters to find the optimal range amount of the solution that will achieve maximal disinfection with minimal waste of the agents while simultaneously preserving the food quality and safety for consumption (*also see MPEP 2144.05*).

11. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doyle or Wright in view of Bo.

As discussed above, Doyle, Wright, and Bo each teach a process that meets the limitations of Claim 1.

Neither Doyle nor Wright specifically discloses that the liquid composition is applied in an amount from 0.5 to 10, and further 1 to 3 liters per ton of plant material.

However, as discussed above, Bo teaches that the liquid composition is applied in an amount of 5 liters per ton of plant material.

However, the Examiner takes the position that the level and completeness of disinfection of the food material will depend both on the type of plant material, and the liquid composition,

Art Unit: 1794

concentration and the pH of the chemical agents, in the liquid solution, and further, the dilution of the concentrated liquid solution used.

It would have therefore been obvious at the time the invention was made it would be obvious to one having ordinary skill in the art to modify the process of Doyle or Wright by applying the liquid disinfecting composition in the amount of 5 liters per ton as taught by Bo, because as taught by Bo, this amount of an aqueous peroxide and organic acid containing solution is effective in disinfecting and preserving plant materials for animal feed.

Additionally, in an analogous art of inhibiting microbial growth in foods, Nakanishi discloses addition of benzoic acid and its salts in combination with other disinfectants or preservatives such as sorbic acid, acetic acid and its derivatives, and hydrogen peroxide (*Col. 1, lines 22-26; Col 2, lines 54-71*), and that when an antimicrobial agent is added to foods, including fruits and vegetables (*Col 2, lines 21-41*), it must have low toxicity to humans and/or animals and should have no adverse effect upon the flavor of the foods at the levels at which they are employed (*Col 1, lines 60-64*).

It would have therefore further been obvious at the time the invention was made it would be obvious to one having ordinary skill in the art to modify the process of either Doyle or Wright by adjusting the amount of the liquid composition used to treat the plant material from 1 to 3 liters because addition of such agents to food for human or animal consumption must be in an amount that has no adverse effect upon the flavor of the foods and present little to no toxicity, and thus it would be within the level of ordinary skill to modify such parameters to find the optimal range amount of the solution that will achieve maximal disinfection with minimal waste

Art Unit: 1794

of the agents while simultaneously preserving the food quality and safety for consumption (*also see MPEP 2144.05*).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. **Chen et al. (5,641,530):** Chen discloses a method of disinfection of foodstuff involving the use of a hydrogen peroxide in combination with the anti-microbial agent benzoic acid, where the combination of such chemicals has a synergistic antimicrobial effect and gives superior disinfection of food compared to combinations of hydrogen peroxide with other agents (*Abstract; Col 1, lines 4-8; Col 2, lines 30-34 and 46-67*).
- b. **Carr et al. (US Pat. No. 6,207,108)** teaches the disinfecting of a food product with a peracid and peroxide containing solution (see Claim 21).
- c. **French et al. (US Pat. No. 5,545,374)** teaches a disinfection aqueous solution of peracetic acid and peroxide particularly intended for use in the food, beverage, and allied industries including food and drink intended not only for human consumption but also intended for consumption by livestock, and pets.
- d. **Malone et al. (US Patent No. 6,295,759)** discloses a process of cultivating hydroponic plants wherein the water solution used contains a disinfectant comprising peracetic acid, hydrogen peroxide, and acetic acid.

Art Unit: 1794

- e. **PERICIDE® EF MSDS (Published 12/10/01):** A commercially available disinfecting agent (biocide) containing 5% peracetic acid, 22% hydrogen peroxide, and 10% acetic acid.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to APRIL C. INYARD whose telephone number is (571) 270-1245. The examiner can normally be reached on Monday - Thursday 8:00 AM - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571) 272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David R. Sample/
Supervisory Patent Examiner, Art Unit 1794

APRIL C INYARD /A. C. I./
Examiner, Art Unit 1794